

REMARKS/ARGUMENTS

The January 2, 2004 Office Action has rejected all claims under 35 U.S.C. § 112. In light of the amendments above and the arguments below, Applicants respectfully request reconsideration.

§ 112 Rejections

Claims 1, 3 - 9 and 11 - 13 are rejected under 35 U.S.C. § 112, first paragraph on the ground that the specification is not enabling for current claim scope. The Office Action suggests alternative claim language.

Applicants disagree with the Examiner's analysis of the specification but have presented modified claims in the interests of speedy prosecution. The Office Action has suggested that Applicants limit step (c) to culturing the embryoid bodies in a medium "consisted of DMEM/F12, insulin, transferrin, progesterone, putrescine, sodium selenite, heparin and an effective amount of fibroblast growth factor 2, wherein neural precursor cells are generated and wherein neural precursor cells form rosette formations". Applicants are unsure if the Examiner's language is meant to encompass "consisting of" or "comprised of."

To hasten prosecution, Applicants have presented two new claims that are meant to comply with the Examiner's

suggestion. Claim 18 is drafted to a medium "consisting essentially of" the Examiner's elements. Applicants believe that the "consisting essentially of" is correct as it directly prohibits a third party from adding inessential extra elements and defeating Applicants' claim scope. Applicants note that the "consisting essentially of" language is well characterized in the patent art and

"is a transition phrase commonly used to signal a partially opened claim in the patent. Typically 'consisting essentially of' precedes a list of ingredients in a composition claim . . . by using the term 'consisting essentially of' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention" PPG Industries v. Guardian Industries Corp. (1998) 156 F.3d 1351.

Claim 19 is drawn to a medium "comprising" the different elements suggested by the Examiner. Applicants have added an additional element—"in the absence of other proliferation/differentiation agents." Applicants recognize that their invention is the use of fibroblast growth factor 2 as the only proliferative element. Note specification paragraphs [0028] and [0029] where Applicants refer to fibroblast growth factor as a proliferation/differentiation element and refer to cells cultured in the media without FGF2 as not differentiating or proliferating. Applicants also note the specification, paragraph [0021], where the "formation of

neural tube-like structures was noted in the majority of EBs in the presence of FGF2 . . . in the absence of FGF2, no well-organized rosettes were observed." This limitation distinguishes prior art use of proliferation/differentiation agents such as retinoic acid.

Applicants believe these two claims to be allowable.

Claim 1 has been drafted to define step (c) as containing cell culture medium and a single proliferation/differentiation agent, fibroblast growth factor 2. Applicants assert that the cell culture aspects of the media are simply cell culture components known to one of skill in the art. Applicants draw the Examiner's attention to specification paragraph [0014] where

"the EBs are then cultured in medium containing fibroblast growth factor 2 (FGF2). The preferable components of the medium are as described below. However, many other medium components are suitable. A suitable medium is any medium used for growing neural cells. References 8 - 11, 14, 15 and 18 - 20 use the same or similar mediums"

The invention here is the use of the proliferative agent FGF2 in any standard cell culture medium with the absence of other proliferative agents. Applicants have presented a great deal of evidence in the current prosecution to demonstrate that Applicants' culture conditions result in a unique product.

Claim 10 is rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement

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requirement. The Examiner notes that it is unclear whether the recited human ES cell lines are readily available to the public or that written instructions are sufficient to reproducibly construct this biological material. Applicants disagree with the Examiner's characterization of the specification, but have cancelled claim 10 in the interest of speedy prosecution.

No fee is believed necessary to enter this response. However, if any fees are necessary, please charge Deposit Account 17-0055.

Respectfully submitted,

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